

Improving HPV Vaccination Uptake

It's time we got it right....

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Objectives

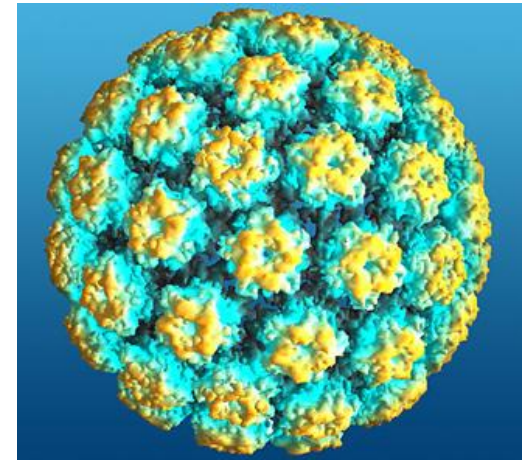
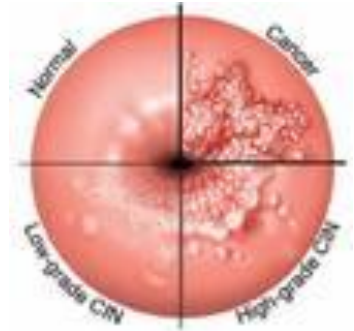
- Learners will be able to:
- Describe the health impact of HPV
 - Describe the impact HPV vaccination has had to date on HPV infection
 - and correlation with long term disease reduction
- Respond to parental concerns re: HPV vaccine with evidenced-based information
- Identify at least 2 strategies to improve HPV vaccine series completion

Disclosure

- I have no financial relationships with a product or commercial manufacture to disclose
- I will not discuss and off label use of medications or other products

Human Papilloma Virus

- Over 100 serotypes cause human disease, 40 in the genital tract
- 2 serotypes responsible for 70% of cervical dysplasia/cancer- 16/18
 - HPV is “necessary but not sufficient for all cervical cancers”
- 2 serotypes responsible for 90% of genital warts-6/11
 - Also seen in oral, nasal, laryngeal and conjunctival warts
- assoc with other anogenital cancers and respiratory tract papillomas in infants



HPV

- Approximately 79 million Americans are currently infected with HPV
 - Another 14 million become infected each year
 - >50% of sexually active men and women will get at least one type of HPV at some time in their lives
- 90% of HPV infections spontaneously disappear in 2 years

Genital warts and infectivity

- Sexually transmitted disease
 - Transmission can occur without visible warts
- Risk decreases with condom use but is not 100%
 - Warts can occur in areas not covered by condom
- Risk of transmission decreased after ablative treatment
 - But may not totally eradicate risk of transmission
- Treatment is for comfort of patient
 - May recur within first 3 mos

HPV and Cancer

Type of Cancer	% association with HPV
Cervical	Almost 100% (16, 18 = 66%)
Vulvar	50%
Vaginal	65%
Penile	35% (16 = 72%; 18, 33, 35 5% each)
Anal	95% (16, 18 = 79%)
Oropharyngeal	60% (plus cofactors of alcohol and tobacco use)

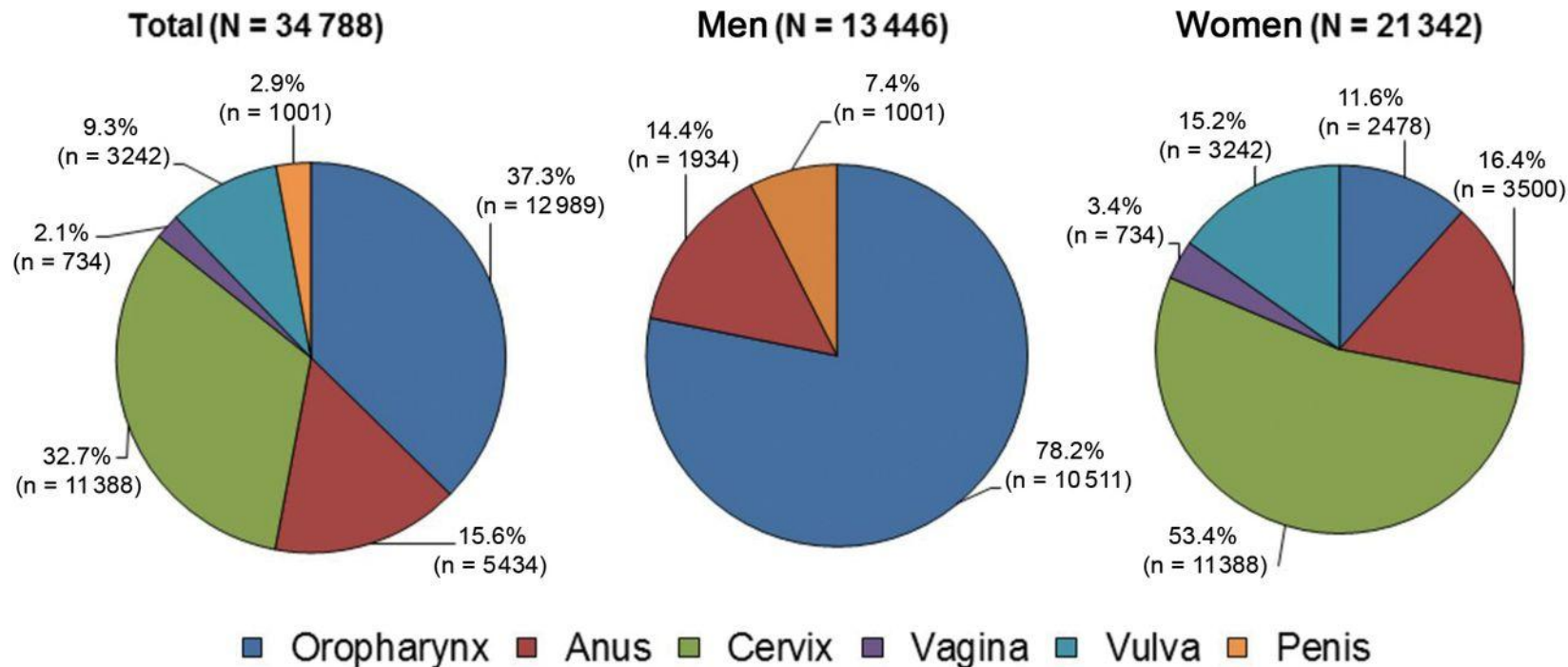
HPV and transmission

- Concordance between HPV found in cervix and anal canal in heterosexual women
 - ? Hand inoculation
 - Ano-genital self inoculation
- HPV infection duration unclear
 - Infection may be long lasting
 - Not necessarily an indication of infidelity in a relationship
- Significant increase in HIV infection
 - Transmission risk may be a function of sexual practices

HPV and diseases

- Incidence per year
 - 360,000 persons in the US get genital warts
 - 10,300 women in the US get cervical cancer
 - 2100 vulvar cancers
 - 500 vaginal cancers
 - 600 penile cancers
 - 2800 anal cancers in women, 1500 in men
 - 1700 oropharyngeal cancers in women, 6700 in men (alcohol and tobacco use play a high role in these cancers)
- ESTIMATE 21000 cases per year preventable with HPV vaccination

Number of new human papillomavirus (HPV)–associated cancers overall, and by sex, in the United States, 2009.



Jemal A et al. JNCI J Natl Cancer Inst 2013;105:175-201

HPV vaccines

- 2 licensed vaccines
 - Quadrivalent HPV Gardasil® Merck
 - HPV 6,11,16,18
 - Only vaccine licensed for use in males
 - Evidence of protection against cancers of vagina, vulva, and anus as well as genital warts, and possibly some penile cancers caused by HPV 16.
 - Bivalent HPV Cervarix® GSK
 - HPV 16, 18

HPV Vaccine

Advisory Committee on Immunization Practices (ACIP)
recommendations:

- 2006, quadrivalent vaccine licensed and recommended for females ages 9-26 years
 - Protects against cervical cancer and genital warts
- 2009, bivalent vaccine licensed and recommended for females ages 9-26 years
 - Protects against cervical cancer only
- 2009, *permissive recommendation* for use in males ages 9-26 years
- 2011 recommended all males 11-12yo (9-21yo routine, 22-26yo permissive)
 - Quadrivalent vaccine only

***The U.S. Advisory Committee on
Immunization Practices recommends:***

- Routine vaccination of females ages 11 or 12 years with three doses of either Cervarix® or Gardasil®. The vaccination series can be started beginning at age 9 years. Vaccination is recommended for females ages 13 through 26 years who have not been vaccinated previously or who have not completed the three-dose series.
- Routine vaccination of males* ages 11 or 12 years with Gardasil® administered as a three-dose series. The vaccination series can be started beginning at age 9 years. Vaccination with Gardasil® is recommended for males ages 13 through 21 years who have not been vaccinated previously or who have not completed the three-dose series. Males ages 22 through 26 years may be vaccinated.

Interim data

- Australia- coverage 80%
- Survey of 18-24 yo women presenting to FP clinic
 - 202 women pre vaccine/404 post vaccine era
 - 57 unvaccinated, 338 vaccinated
 - Reduction of prevalence of 4 vaccine serotypes 28.7 % pre vaccination (2005-2007) to 6.7% post vaccination (2010-2011)
 - Reduction in **vaccinated and unvaccinated** women in post vaccination cohort

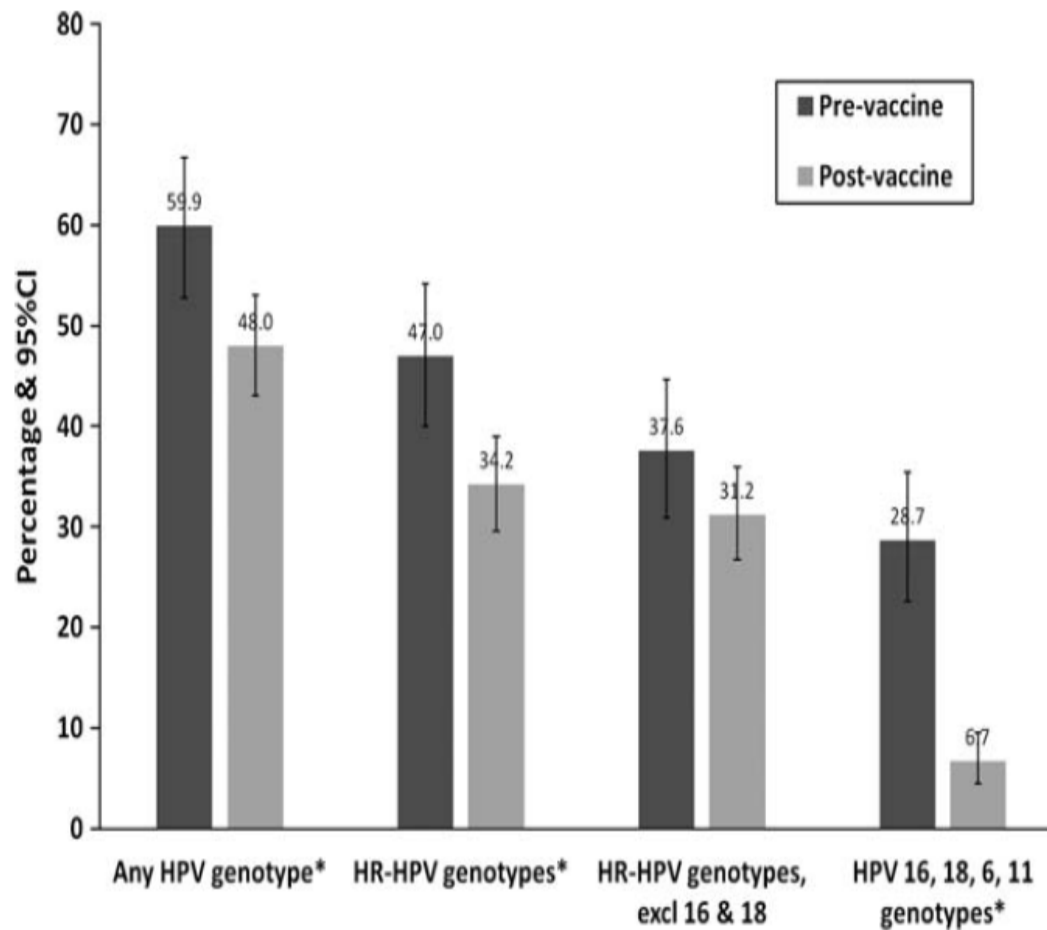


Figure 1. Differences in human papillomavirus (HPV) genoprevalence between prevaccine and postvaccine populations. * $P < .05$ for difference in percentages between groups. Abbreviations: CI, confidence interval; excl, excluding; HR-HPV, high-risk HPV.

Interim data- US

- Review article of published data on HPV reduction post vaccine era
 - International review of studies from 6 countries: Sweden, Denmark, Germany, Australia, New Zealand, US
- US data from 3 “ecological studies” pre and postvaccination cohorts
 - 56-79% reduction in vaccine serotypes in self collected vaginal samples from all women
 - More significant prevalence decrease in women who had been vaccinate
 - No decrease seen in older women in era when only teens were being vaccinated

Hariri, et al “Population Impact of HPV Vaccines:
Summary of early evidence”
J Adol Health 2013 Dec 53(6): 679-82

Interim data -US

- Study in Indiana
 - 14-17yo high risk teens
 - 150 Historical controls/75 prospectively recruited young women – historical case control study
 - 9.5x higher RR of HPV of 4 vaccine serotypes in unvaccinated historical controls than vaccinated PC
 - 2 or more vaccines
 - 5.6x higher RR compared to whole PC cohort
 - Fewer sexual encounters without a condom in vaccinated teens
 - No other differences in sexual behavior
 - #episodes intercourse, # sexual partners, other STIs

Interim data- US

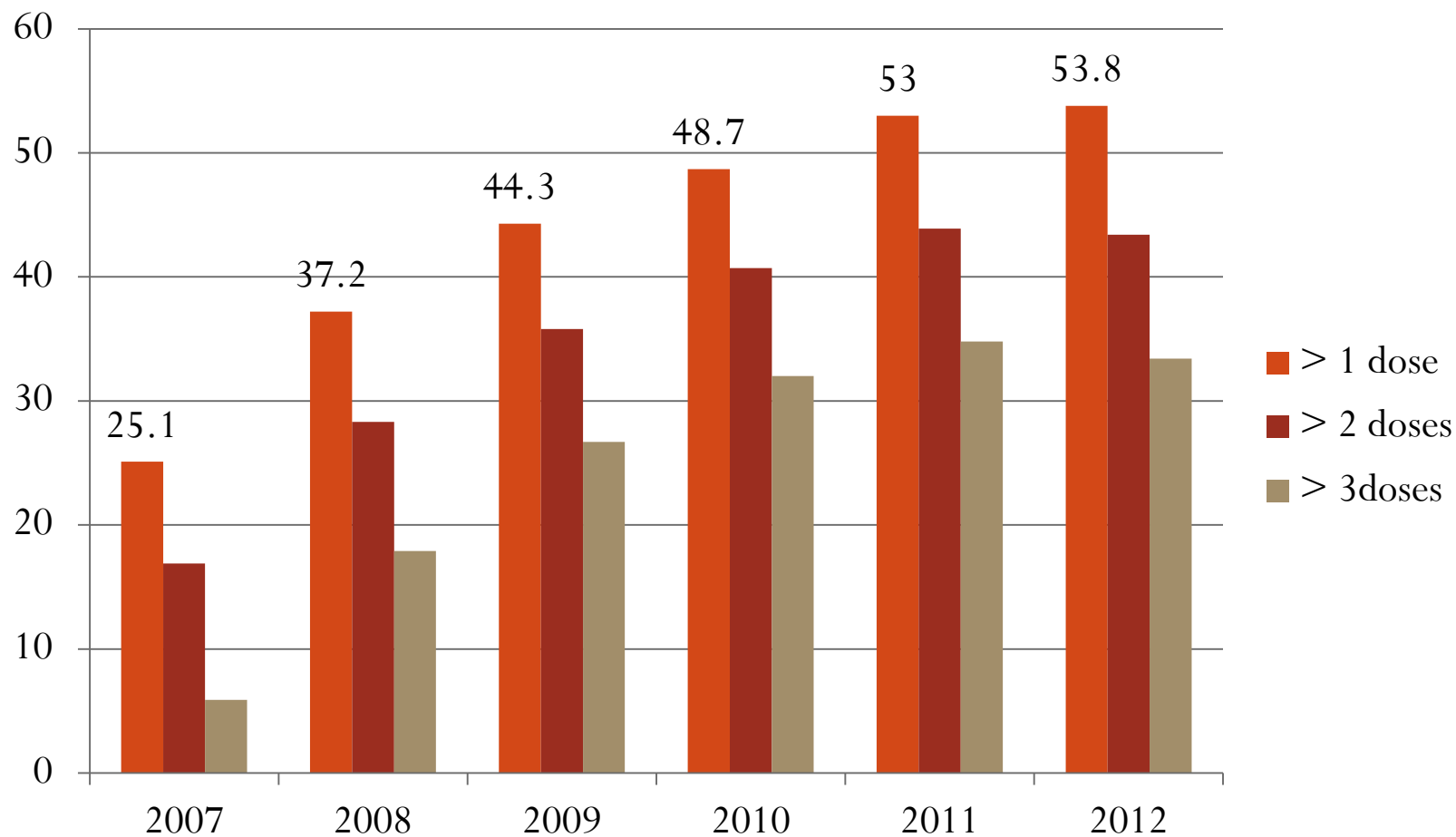
- 3 studies show significant reductions in reports of genital warts in pre vs. post vaccination cohorts
 - Primary effect in young men and women who were vaccinated
- Some “herd immunity” effect seen in all studies with unvaccinated women also showing reduction in detected infection and disease
- Evidence of some protection even with only one dose of vaccine
 - Improved outcome with increased number of doses

Healthy People 2020

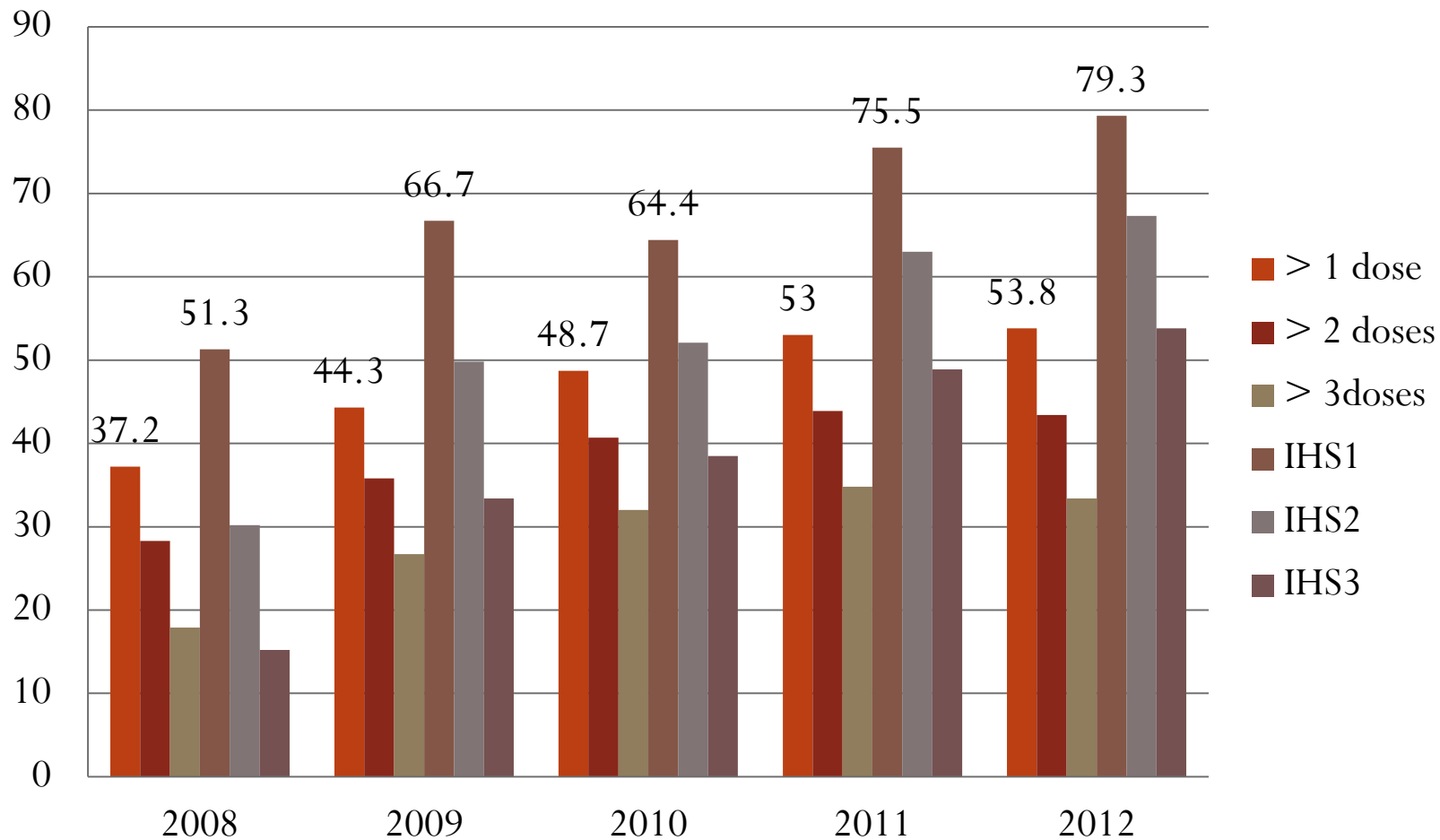
80% of 13-15 yr girls fully immunized with HPV vaccine

“For each year that vaccination rates among girls stay at 30% instead of 80%, 4,400 future cervical cancer cases and 1,400 cervical cancer deaths will occur.” - Dr. Tom Frieden, Director of the Centers for Disease Control and Prevention (CDC)

HPV coverage -US



US vs. IHS HPV coverage-girls



Feb 10, 2014

- President's Cancer panel issues challenge
 - Accelerating HPV Vaccine uptake-Urgency for Action to Prevent Cancer
 - Goal # 1 Reduce missed opportunities to recommend and administer HPV vaccines
 - Goal # 2 Increase Parents', Caregivers' and Adolescents' acceptance of HPV vaccine
 - Goal # 3 Maximize access to HPV vaccination services
 - Goal # 4 Increase global HPV vaccination

<http://deainfo.nci.nih.gov/advisory/pcp/annualReports/HPV/Part1Section3.htm#sthash.2jxu0k98.dpbs>

Barriers to immunization

- Missed opportunities
 - Provider does not offer
 - Provider does not provide clear recommendation
 - Parent misinformation
- Lack of Medical home?
 - Alternative venues for immunization
- Cost of vaccination
 - AI/AN categorically eligible under VFC program

Missed Opportunities

1. Providers don't offer
2. Providers don't offer a clear recommendation

Factors Contributing to Providers' Hesitancy

- Limited understanding of HPV-associated diseases and benefits of HPV vaccination, particularly for males
- Concerns about safety
- Concerns about inadequate reimbursement for vaccines
- Personal attitudes and beliefs
- Discomfort talking to parents and adolescents about a topic related to sexual behavior

Provider Hesitancy (cont)

- Concerns about parental resistance
- Preference for vaccinating older versus younger adolescents
- Lack of time or incentives to educate parents and patients about HPV and HPV vaccines
- Lack of systems to remind providers to offer vaccines to age-eligible patients

HPV vaccine offers by provider specialty

- National survey of Pediatricians, Family Med, OB-GYN providers
 - More recommendations and increased acceptance with physician perception of decreased barriers
 - More likely to recommend to older adolescents
 - 32.8% of early adolescents, >50% of middle/older adolescents
 - OB-GYN providers
 - 35% of women 18-21 use OB-GYN providers for preventive health care
 - Big role in providing immunizations for young adult women
 - We, the providers, create missed opportunities!

Missed Opportunities

1. Parent misinformation
2. Provider misinformation

Bachmann claims HPV vaccine might cause 'mental retardation'

The Washington Post, Posted by [Rachel Weiner](#) at
11:02 AM ET, 09/13/2011



“HPV Vaccine Controversy”

Katie Couric show

Dec. 4 and Dec. 6, 2013



Safety of HPV vaccine

- As of March 2013-CDC analysis/IOM
 - 57 million doses
 - 22,000 adverse events
 - 92% “non serious”
 - Fainting, dizziness, nausea, headache, fever, urticaria
 - Local reaction at injection site, redness, swelling, pain
 - 8% “serious”
 - Guillian Barre, venous thromboembolism, stroke, chronic fatigue, nausea, autoimmune disease, death
 - No more common post vaccination than in matched control group of same age
 - Fainting more common
 - 15 min waiting period post injection

Safety of HPV vaccine

- Japan suspended recommendation for vaccine June 2013
- Continues to offer as part of universally funded vaccine program
- Concern over adverse effects: “complex regional pain syndrome”
- 12.8 reports/ 1 million doses
 - higher than influenza/IPV
 - Lower than Japanese encephalitis vaccine

Safety of HPV vaccine

- Arnheim-Dahlstrom et al BMJ Oct 9 2013 347
- Cohort study Sweden Denmark
- Over 690,000 doses studied with > 290,000 recipient girls ages 10-17yo
- 53 different outcomes examined: autoimmune, neurologic, VTE
- No temporal association found within 180 d of qHPV vaccine administrations

Reasons Parents Did Not Intend to Vaccinate Their Adolescents Against HPV

- Vaccination not needed, particularly for males
- Vaccination not recommended by healthcare provider
- Safety concerns
- Lack of knowledge about the vaccines or diseases caused by HPV infections
- Son or daughter not sexually active
- Son or daughter too young to be vaccinated against HPV
- Cost of vaccines

How young is “too young”?

- Likelihood of sexual debut
 - YRBS data 1999-2007
 - Self reporting
 - Cavazos-Rehg, et al “Age of Sexual Debut Among US Adolescents” Contraception. Aug 2009; 80(2): 158–162.
- Efficacy of HPV vaccine improves if given before “sexual debut”

Age of first sexual intercourse	n	%
Never had sexual intercourse	32,032	47.89
11 years old or younger	2170	3.24
12 years old	2062	3.08
13 years old	3802	5.69
14 years old	6167	9.22
15 years old	6779	10.14
16 years old	5146	7.69
17 years old or older	2539	3.80
Missing	6186	9.25

What do they want to know?

- Cincinnati Children's Hospital
- 33 mother/11-12yo daughter pairs
 - Interview within 2 d of receiving 1st HPV
 - Interview as to
 - What did the provider tell them?
 - What did they want the provider to tell them?
- Information about safety and efficacy important to mom and daughter
- Lack of concordance in recall of mom and daughter about discussions of sexual activity and sexual health

What we say to dogs

Okay, Ginger! I've had it!
You stay out of the garbage!
Understand, Ginger? Stay out
of the garbage, or else!



What they hear

blah blah GINGER blah
blah blah blah blah
blah blah GINGER blah
blah blah blah blah...



Impact of what providers say

1. The information we give
2. The way we give it- “presumptive vs. participatory”

Influence of provider recommendation on vaccine acceptance

- Multiple studies with
 - Childhood vaccines
 - Vaccines in pregnancy
 - Adolescent vaccines
 - HPV has lowest acceptance of all adol vaccines
- Message: Presumptive vs. Participatory
 - 47% of “Vaccine hesitant parents” will change their mind if given
 - Education
 - Presumptive recommendation from provider
 - “we have to do some shots” vs. “what do you want to do about shots?”

HPV vaccines should be framed as vaccines that prevent cancers

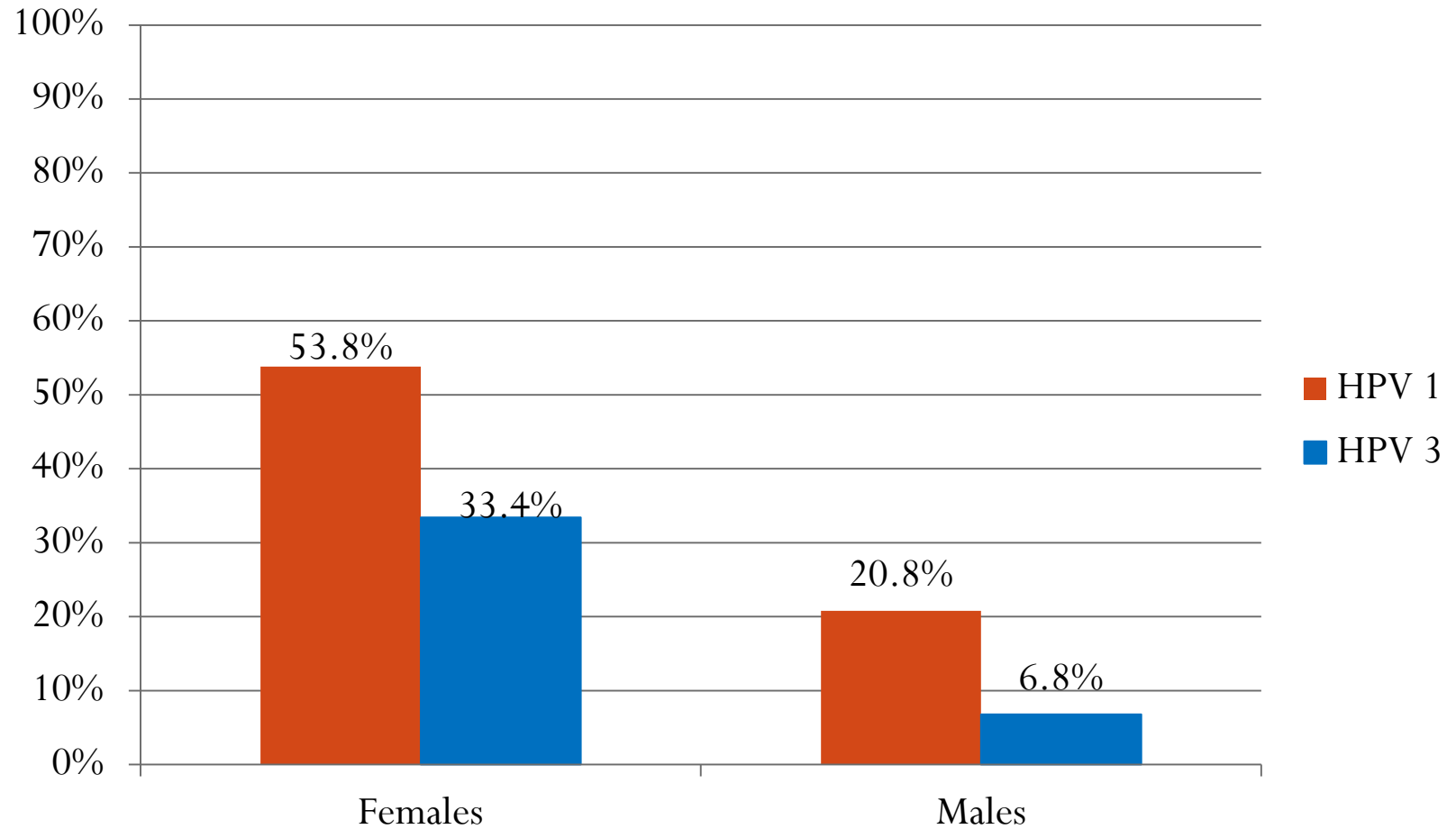
Not all cancers....but many forms of cancer in men
and women

PREVENTION !!

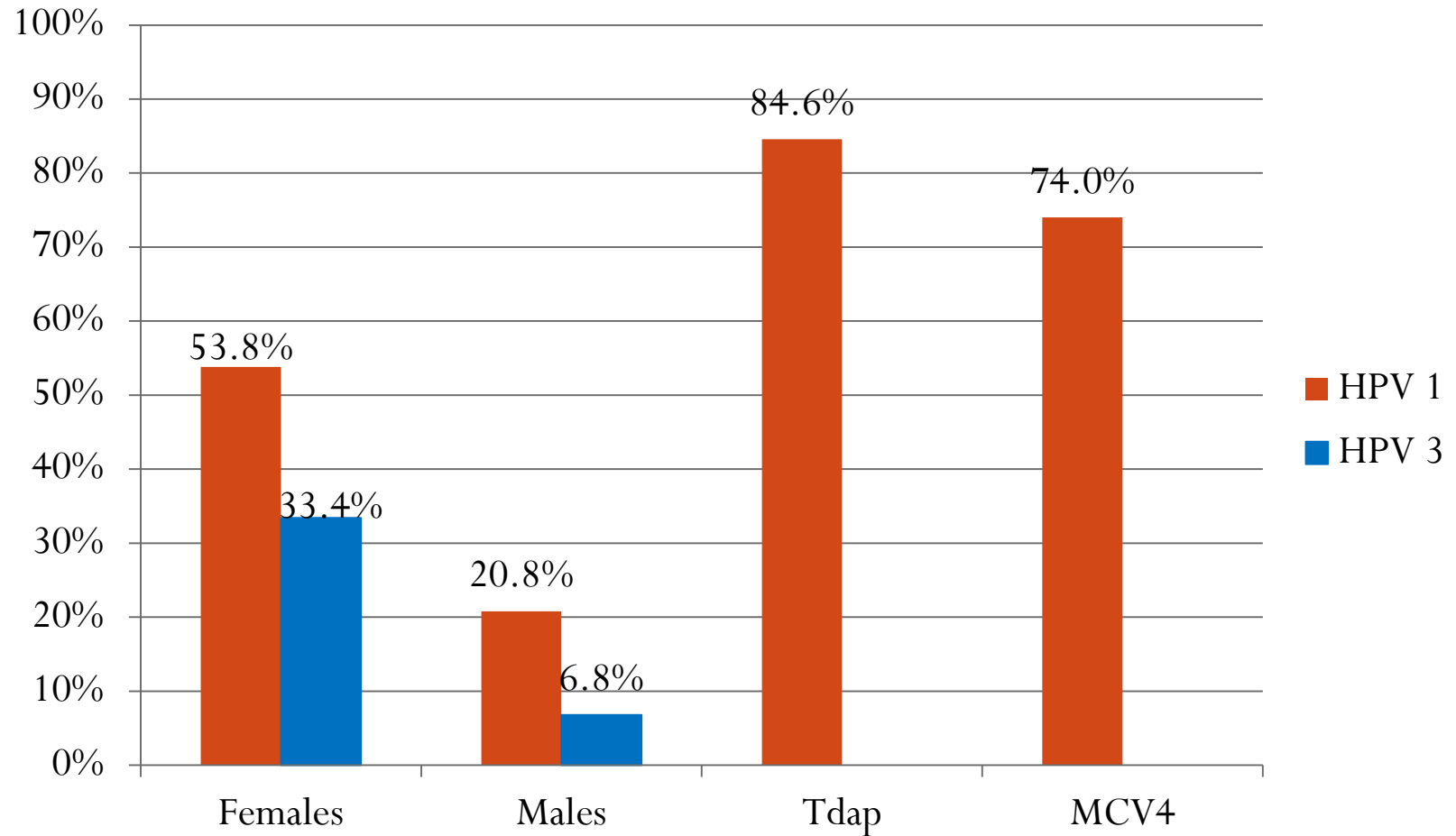
Missed opportunities

Why do we treat HPV differently than Tdap or
MCV4?

U.S. HPV Vaccine coverage data 13-17 year olds

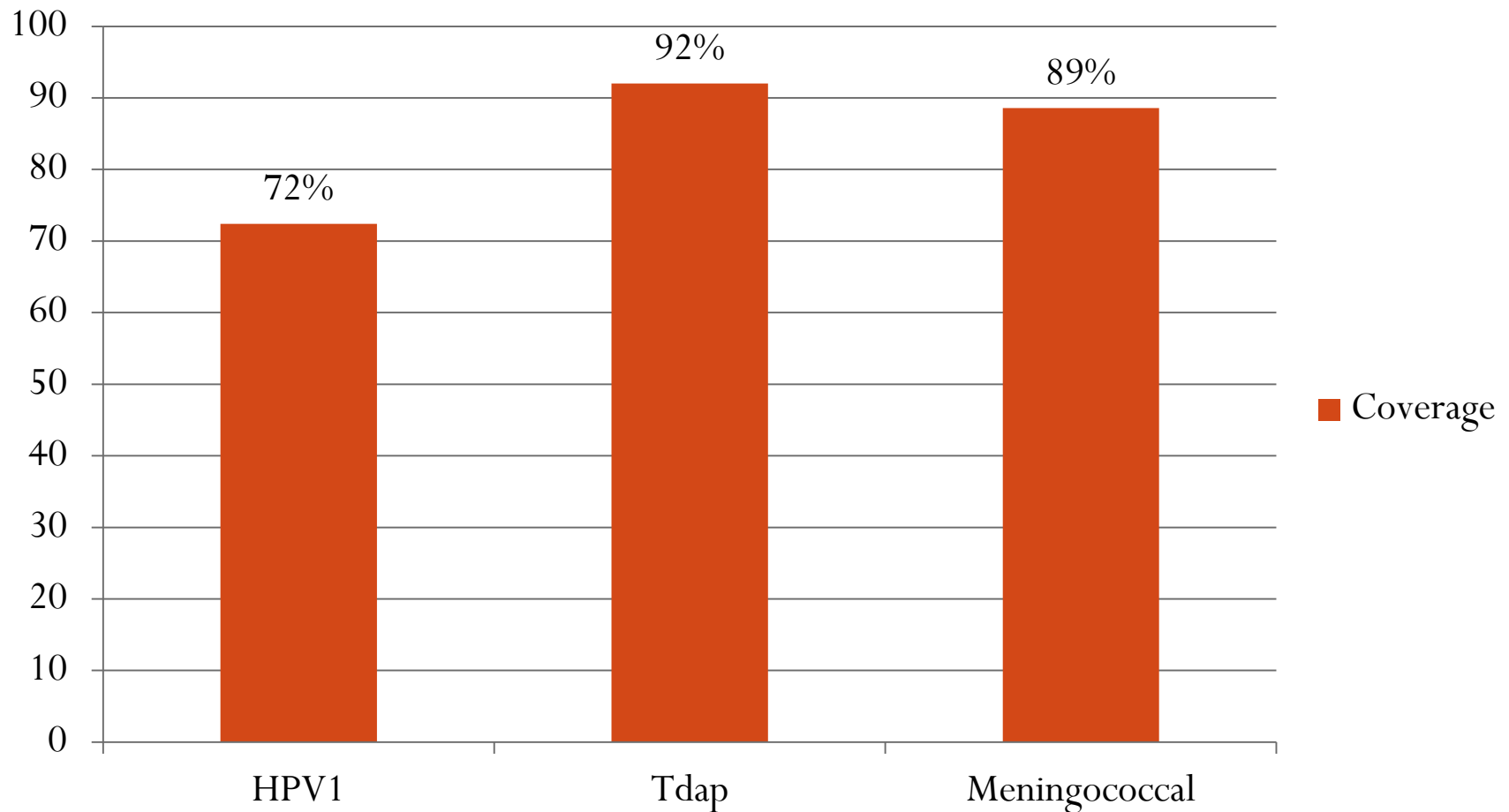


U.S. HPV Vaccine coverage data 13-17 year olds



IHS vaccine coverage

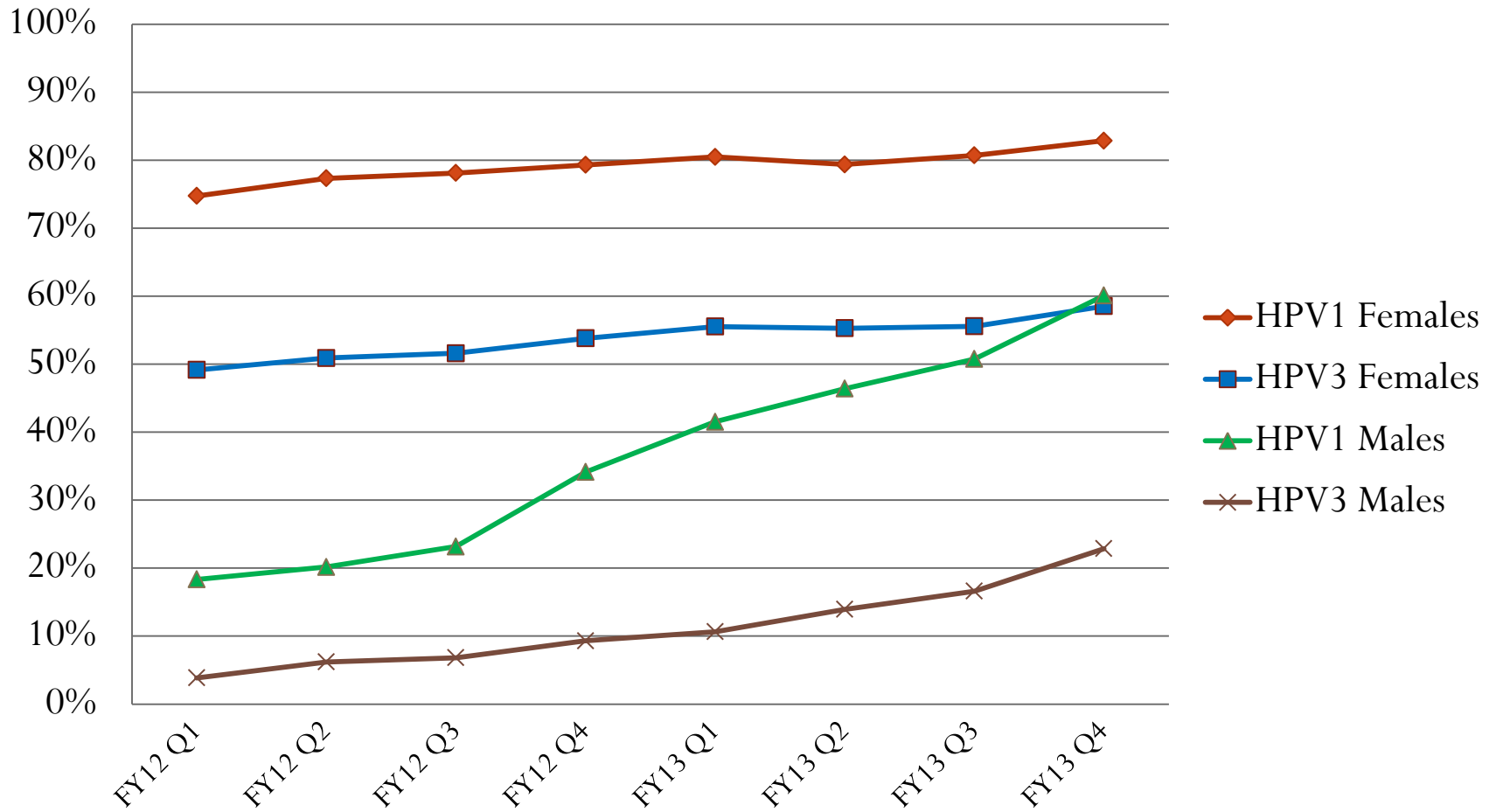
Adolescents 13-17 years, Dec. 31st 2013



Reduce Missed Opportunities

- Offer vaccines at ALL visits (not just preventive care visits)
- Simultaneous administration of all adolescent recommended vaccines
- Compare HPV 1 coverage to coverage with Tdap and meningococcal

IHS HPV1 and HPV3 coverage Females and Males, 13-17 years



Provide a **STRONG** recommendation

- Focus on HPV vaccines as a tool to prevent multiple cancers.
- Emphasize the importance of vaccinating both males and females.
- Emphasize the importance of vaccinating the primary target age group (11- to 12-year-olds).
- Promote catch-up vaccination for older adolescents and young adults, as needed.
- Reinforce HPV vaccine efficacy and safety.
- Encourage administration of HPV vaccines as part of an adolescent vaccine platform. Unless contraindicated, HPV vaccines should be administered at the same time as other adolescent vaccines

Missed Opportunities

Recall / Reminder systems

Immunization notifications

- Automated/computerized- EHRs
- ASIIS
- Indian Health Service: RPMS
 - Forecasting program
 - Forecast seen by all elements of the care system
 - ED, urgent care, primary care, inpatient
 - Standing orders for nursing
 - Screening patients at non well child visits
 - Reappointments for subsequent doses
 - Nurse only visits
- Merck reminder stickers/refrigerator magnets/postcards/telephone calls
- <https://www.merckvaccines.com/Professional-Resources/Pages/OutreachProgramForVaccineSeriesCompletion>

Patient: [REDACTED] DOB: 11-Apr-2001 (13 yrs)
Chart#: [REDACTED] Active Male M HBsAg: UNK

#	Immunization History		Immunizations DUE on 04/16/2014
1	06/18/01 DTaP	Phoe	Tdap due
2	08/13/01 DTaP	Phoe	MENING-CV4 past due
3	10/11/01 DTaP	Phoe	HPV-4 past due
4	08/27/02 DTaP	Phoe	
5	04/13/05 DTaP	Tuba	Last Letter: 05-Aug-2011
6	06/18/01 IPV	Phoe	
7	08/13/01 IPV	Phoe	
8	10/11/01 IPV	Phoe	
9	04/13/05 IPV	Tuba	
10	06/18/01 PEDVAXHIB	Phoe	

+ Scroll down to view more. Type ?? or Q to QUIT.

A Add Immunization	D Delete Visit	P Patient Edit
S Skin Test Add	I ImmServe Profile	C Contraindications
E Edit Visit	H Health Summary	L Letter Print

Select Action: Quit//

Vaccination Forecast

The forecast automatically switches to the accelerated schedule when a patient is behind schedule.

Vaccine Family	Dose	Recommended Date	Minimum Valid Date	Overdue Date	Status
FLU	1	07/20/2005	07/20/2005	08/19/2005	Past Due
VARICELLA	2	07/20/2005	07/20/2005	04/11/2006	Past Due
HPV	1	04/11/2012	04/11/2010	04/11/2014	Past Due
MENINGOCOCCAL	1	04/11/2012	04/11/2012	04/11/2014	Past Due
Tdap	1	04/11/2012	04/11/2012	05/11/2014	Due Now

* DTaP or DT should be given to patients under 7 years of age. One dose of Tdap should be administered to underimmunized children 7 years of age and older or as a booster dose. Td should be administered when appropriate.

** If an adolescent has already begun the routine 3 dose Hep-D schedule, they should not be changed to the 2 dose schedule.

Due Now – As of today's date, the patient's age falls between the recommended minimum age and the recommended maximum age for this dose and the absolute minimum interval has been met since the last dose.

Past Due – As of today's date, the recommended maximum age or the recommended maximum date for this dose has passed.

Up to Date – As of today's date, the patient is not due or past due.

Optional – This vaccine may be administered today. Although the usual "recommended" date has not been met, the minimum valid date for this dose has been met.

Removing Financial Barriers

How to fund a very expensive vaccine

- \$130 per dose
- VFC program
 - If ACIP recommends the vaccine, it becomes part of the covered vaccine package for VFC recipients
 - Native Americans categorically eligible
 - Medicaid/CHIP eligible
- ACA —
 - All private insurance plans cover all ACIP recommended vaccines
 - All state exchange plans cover all ACIP recommended vaccines
- Merck/GSK assistance plans for uninsured young adults
 - >19 yr old, uninsured or insurance does not cover

Increase Access

- Walk-in immunization clinic hours
- Pharmacy-based vaccination
 - ARS 32-1974 certified pharmacists may administer HPV vaccine with a prescription
 - Report within 48 hours to primary care provider
 - Record keeping required/reporting to ASIIS
 - Emergency resuscitation preparedness required
 - Authorizes immunization of children >6yo but < 18 yo as well as adults
- School-based vaccination

School based vaccination

- Used in many international venues
- School based health services
 - Adolescent health services
- Separate school based vaccination clinics
- Issues to address
 - Accurate information to parents-VIS
 - Consent documentation
 - Reimbursement

Coming Soon . .

- 9 - valent HPV vaccine
 - Merck product
 - Protects against 5 additional HPV strains
 - 31,33,46,52,58
 - 20% of cervical cancers
 - Currently under licensure review
 - ACIP vote expected in February 2015

The Advisory Committee on Immunization Practices (ACIP)

- Federal advisory committee to HHS/CDC
- Develops written recommendations for the routine administration of vaccines to children and adults in the U.S.
- Determines which vaccines should be included in the VFC program
- Made up of medical and public health experts
 - 15 voting members
 - Ex-officio representatives (including IHS)
 - 30 professional organizations (e.g. AAP, AAFP, ACP, ACOG, etc.)
- Conduct exhaustive review of vaccine research
 - Safety, effectiveness, cost, epidemiology, public health impact, etc.

Resources

- CDC “You are the Key to Cancer Prevention” - HPV resources for providers
 - Fact sheets for talking with hesitant parents
 - Patient education materials
 - Podcasts
 - Radio PSAs
 - Webinars with CMEs

<http://www.cdc.gov/vaccines/who/teens/for-hcp/hpv-resources.html>

- Merck Reminder/Recall program, magnets

“Hit me with your best shot, fire away!”

Pat Benatar
Crimes of Passion, 1979

